# EXHIBIT A

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
NANCY HERSH, ESQ.
HERSH & HERSH, A Professional Corp.
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102-6396
TELEPHONE NO.: (415) 441-5544 FAX NO.:
ATTORNEY FOR (Name): Plaintiff
CALIFORNIA STATE BAR 49091

FOR COURT USE ONLY

FILED
San Francisco County Superior Court
MAY 11 2007
GORDON PARK-LI, Clerk
BY: Param Natt Deputy Clerk

IMAGED AUG 28 2007

SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO
STREET ADDRESS: 400 McAllister Street
MAILING ADDRESS: San Francisco, CA 94102
CITY AND ZIP CODE:
BRANCH NAME: Unlimited Jurisdiction

CASE NAME: VICENTE v. ELI LILLY AND COMPANY

CASE NUMBER: CGC-07-463338
JUDGE:
DEPT:

## CIVIL CASE COVER SHEET

[√] Unlimited (Amount demanded exceeds $25,000) [ ] Limited (Amount demanded is $25,000 or less)

**Complex Case Designation**
[ ] Counter [ ] Joinder
Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

*Items 1–5 below must be completed (see instructions on page 2).*

1. Check **one** box below for the case type that best describes this case:

**Auto Tort**
- [ ] Auto (22)
- [ ] Uninsured motorist (46)

**Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort**
- [ ] Asbestos (04)
- [ ] Product liability (24)
- [ ] Medical malpractice (45)
- [ ] Other PI/PD/WD (23)

**Non-PI/PD/WD (Other) Tort**
- [ ] Business tort/unfair business practice (07)
- [ ] Civil rights (08)
- [ ] Defamation (13)
- [ ] Fraud (16)
- [ ] Intellectual property (19)
- [ ] Professional negligence (25)
- [ ] Other non-PI/PD/WD tort (35)

**Employment**
- [ ] Wrongful termination (36)
- [ ] Other employment (15)

**Contract**
- [ ] Breach of contract/warranty (06)
- [ ] Collections (09)
- [ ] Insurance coverage (18)
- [ ] Other contract (37)

**Real Property**
- [ ] Eminent domain/Inverse condemnation (14)
- [ ] Wrongful eviction (33)
- [ ] Other real property (26)

**Unlawful Detainer**
- [ ] Commercial (31)
- [ ] Residential (32)
- [ ] Drugs (38)

**Judicial Review**
- [ ] Asset forfeiture (05)
- [ ] Petition re: arbitration award (11)
- [ ] Writ of mandate (02)
- [ ] Other judicial review (39)

**Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)**
- [ ] Antitrust/Trade regulation (03)
- [ ] Construction defect (10)
- [ ] Mass tort (40)
- [ ] Securities litigation (28)
- [ ] Environmental/Toxic tort (30)
- [ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

**Enforcement of Judgment**
- [ ] Enforcement of judgment (20)

**Miscellaneous Civil Complaint**
- [ ] RICO (27)
- [√] Other complaint *(not specified above)* (42)

**Miscellaneous Civil Petition**
- [ ] Partnership and corporate governance (21)
- [ ] Other petition *(not specified above)* (43)

2. This case [ ] is [√] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [ ] Large number of separately represented parties
   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [ ] Substantial amount of documentary evidence
   d. [ ] Large number of witnesses
   e. [ ] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Type of remedies sought *(check all that apply)*:
   a. [√] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [ ] punitive
4. Number of causes of action *(specify)*: 4
5. This case [ ] is [√] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: May 11, 2007
RACHEL ABRAMS
(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

**NOTICE**
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a complex case, this cover sheet will be used for statistical purposes only.



Form Adopted for Mandatory Use
Judicial Council of California
CM-010 [Rev. January 1, 2007]

CIVIL CASE COVER SHEET

4010

Cal. Rules of Court, rules 3.220, 3.400–3.403;
Standards of Judicial Administration, § 19
www.courtinfo.ca.gov

POS-010

| ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): | FOR COURT USE ONLY |
|---|---|
| NANCY HERSH, ESQ.<br>HERSH & HERSH, A Professional Corp.<br>601 Van Ness Avenue, Suite 2080<br>San Francisco, CA 94102-6396<br>TELEPHONE NO.: (415) 441-5544 FAX NO. (Optional):<br>E-MAIL ADDRESS (Optional):<br>ATTORNEY FOR (Name): Plaintiff | FILED<br>San Francisco County Superior Court<br>MAY 21 2007<br>GORDON PARK-LI, Clerk<br>Deputy Clerk |
| SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO<br>STREET ADDRESS: 400 McAllister Street<br>MAILING ADDRESS: San Francisco, CA 94102<br>CITY AND ZIP CODE:<br>BRANCH NAME: Unlimited Jurisdiction | |
| PLAINTIFF/PETITIONER: JAYDEEN VICENTE<br>DEFENDANT/RESPONDENT: ELI LILLY AND COMPANY | CASE NUMBER:<br>CGC-07-463338 |
| **PROOF OF SERVICE OF SUMMONS** | Ref. No. or File No.: |

*(Separate proof of service is required for each party served.)*

1. At the time of service I was at least 18 years of age and not a party to this action.
2. I served copies of:
   a. [√] summons
   b. [√] complaint
   c. [ ] Alternative Dispute Resolution (ADR) package
   d. [√] Civil Case Cover Sheet *(served in complex cases only)*
   e. [ ] cross-complaint
   f. [√] other *(specify documents):* Confidential Cover Sheet-Complaint; Confidential Cover Sheet-Civil Case Cover Sheet
3. a. Party served *(specify name of party as shown on documents served):* Attorney General of California

   b. [ ] Person (other than the party in item 3a) served on behalf of an entity or as an authorized agent (and not a person under item 5b on whom substituted service was made) *(specify name and relationship to the party named in item 3a):*

4. Address where the party was served: 1300 "I" Street, P.O. Box 944255, Sacramento, CA 94244-2550
5. I served the party *(check proper box)*
   a. [ ] **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on *(date):* (2) at *(time):*
   b. [ ] **by substituted service.** On *(date):* at *(time):* I left the documents listed in item 2 with or in the presence of *(name and title or relationship to person indicated in item 3):*

      (1) [ ] **(business)** a person at least 18 years of age apparently in charge at the office or usual place of business of the person to be served. I informed him or her of the general nature of the papers.

      (2) [ ] **(home)** a competent member of the household (at least 18 years of age) at the dwelling house or usual place of abode of the party. I informed him or her of the general nature of the papers.

      (3) [ ] **(physical address unknown)** a person at least 18 years of age apparently in charge at the usual mailing address of the person to be served, other than a United States Postal Service post office box. I informed him or her of the general nature of the papers.

      (4) [ ] I thereafter mailed (by first-class, postage prepaid) copies of the documents to the person to be served at the place where the copies were left (Code Civ. Proc., § 415.20). I mailed the documents on *(date):* from *(city):* or [ ] a declaration of mailing is attached.

      (5) [ ] I attach a **declaration of diligence** stating actions taken first to attempt personal service.



Form Adopted for Mandatory Use
Judicial Council of California
POS-010 [Rev. January 1, 2007]

MacForms (509) 535-4382

PROOF OF SERVICE OF SUMMONS

Code of Civil Procedure, § 417.10

4010

| PLAINTIFF/PETITIONER: JAYDEE CENTE | CASE NUMBER: CGC-07-463338 |
|---|---|
| DEFENDANT/RESPONDENT: ELI LILLY AND COMPANY | |

5. c. ☐ **by mail and acknowledgment of receipt of service.** I mailed the documents listed in item 2 to the party, to the address shown in item 4, by first-class mail, postage prepaid,
   (1) on *(date):* (2) from *(city):*
   (3) ☐ with two copies of the *Notice and Acknowledgment of Receipt* and a postage-paid return envelope addressed to me. *(Attach completed* Notice and Acknowledgement of Receipt.*)* (Code Civ. Proc., § 415.30.)
   (4) ☐ to an address outside California with return receipt requested. (Code Civ. Proc., § 415.40.)

   d. ☑ **by other means** *(specify means of service and authorizing code section):*
   by certified mail, return receipt requested, pursuant to Government Code §12652(c)(3)

   ☐ Additional page describing service is attached.

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. ☐ as an individual defendant.
   b. ☐ as the person sued under the fictitious name of *(specify):*
   c. ☐ as occupant.
   d. ☐ On behalf of *(specify):*
   under the following Code of Civil Procedure section:
   - ☐ 416.10 (corporation)
   - ☐ 416.20 (defunct corporation)
   - ☐ 416.30 (joint stock company/association)
   - ☐ 416.40 (association or partnership)
   - ☐ 416.50 (public entity)
   - ☐ 415.95 (business organization, form unknown)
   - ☐ 416.60 (minor)
   - ☐ 416.70 (ward or conservatee)
   - ☐ 416.90 (authorized person)
   - ☐ 415.46 (occupant)
   - ☐ other:

7. **Person who served papers**
   a. Name: Judy Olasov
   b. Address: 601 Van Ness Avenue, Suite 2080, San Francisco, CA 94102
   c. Telephone number: (415) 441-5544
   d. **The fee** for service was: $ -0-
   e. I am:
   (1) ☑ not a registered California process server.
   (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
   (3) ☐ a registered California process server:
   (i) ☐ owner ☐ employee ☐ independent contractor.
   (ii) Registration No.:
   (iii) County:

8. ☑ **I declare** under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

or

9. ☐ **I am a California sheriff or marshal and** I certify that the foregoing is true and correct.

Date: May 21, 2007

JUDY OLASOV
(NAME OF PERSON WHO SERVED PAPERS/SHERIFF OR MARSHAL)

Judy Olasov
(SIGNATURE)

**SENDER: COMPLETE THIS SECTION**

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Office of the Attorney General
1300 "I" Street
P.O. Box 944255
Sacramento, CA 94244-2550

**COMPLETE THIS SECTION ON DELIVERY**

A. Signature

X Matthew Woods ☐ Agent ☐ Addressee

B. Received by (Printed Name) C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7004 0550 0000 1512 4932

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

EDMUND G. BROWN JR.
Attorney General of the State of California
MARK ZAHNER
Chief Prosecutor
State Bar No. 137732
BRIAN V. FRANKEL
Supervising Deputy Attorney General
State Bar No. 116802
1455 Frazee Road, Suite 315
San Diego, CA 92108
Telephone: (619) 688-6065
Fax: (619) 688-4200
Attorneys for STATE OF CALIFORNIA



SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

**THE STATE OF CALIFORNIA, ex rel. JAYDEEN VICENTE and JAYDEEN VICENTE Individually,**

**Plaintiffs,**

**v.**

**ELI LILLY AND COMPANY,**

**Defendants.**

CASE NO. CGC-07-463338

**STATE OF CALIFORNIA'S NOTICE OF ELECTION TO DECLINE INTERVENTION PURSUANT TO GOVERNMENT CODE SECTION 12652(c)(8)(D)(ii)**

NO HEARING REQUIRED

Dept: 212

Trial Date: None Set
Action Filed: May 11, 2007

**[FILED UNDER SEAL Pursuant to Government Code sections 12652 subdivision (c)(2) and and California Rules of Court, rule 243.6]**

**TO THE SUPERIOR COURT, STATE OF CALIFORNIA:**

PLEASE TAKE NOTICE that pursuant to Government Code section 12652(c)(8)(D)(ii), the Attorney General of the State of California elects to decline intervention in this matter.

///

///

In accordance with the provisions of California Government Code section 12652(f)(1), the Attorney General of the State of California requests that he be served with copies of all future pleadings filed in this action.

Dated: July 9, 2007.

Respectfully submitted,

EDMUND G. BROWN JR.
Attorney General of the State of California
MARK ZAHNER
Chief Prosecutor
BRIAN V. FRANKEL
Supervising Deputy Attorney General

Brian V. Frankel

By BRIAN V. FRANKEL
Supervising Deputy Attorney General
Attorneys for STATE OF CALIFORNIA

**DECLARATION OF SERVICE BY U.S. MAIL**

Case Name: **THE STATE OF CALIFORNIA, ex rel. JAYDEEN VICENTE and JAYDEEN VICENTE v. ELI LILLY AND COMPANY**

Case No.: **CGC-07-463338**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar at which member's direction this service is made. I am 18 years of age or older and not a party to this matter; my business address is: 110 West "A" Street, Suite 1100, San Diego, California 92101.

On July 9, 2007, I served the attached **STATE OF CALIFORNIA'S NOTICE OF ELECTION TO DECLINE INTERVENTION** by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States Mail at San Diego, California, addressed as follows:

**Nancy Hersh, Esq.**
**Hersh & Hersh, APC**
**601 Van Ness Avenue, Ste. 2080**
**San Francisco, CA 94102-6388**
***Counsel for Relator***

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on July 9, 2007, at San Diego, California.

Shakira N. Anderson
Declarant

Signature

# CONFIDENTIAL

MC-060

ATTORNEY (Name, state bar number, and address):
NANCY HERSH, ESQ., SBN 49091
HERSH & HERSH, A Professional Corporation
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102-6388
TELEPHONE NO.: 415-441-5544 FAX NO. (Optional):
E-MAIL ADDRESS (Optional):
ATTORNEY FOR: [✓] PLAINTIFF [ ] OTHER (specify):

FOR COURT USE ONLY

ENDORSED
FILED
San Francisco County Superior Court
MAY 11 2007
GORDON PARK-LI, Clerk
BY: PARAM NATT
Deputy Clerk

SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO
STREET ADDRESS: 400 McAllister Street
MAILING ADDRESS:
CITY AND ZIP CODE: San Francisco, CA 94102
BRANCH NAME: Unlimited Jurisdiction

PLAINTIFF: [UNDER SEAL]

DEFENDANT: [UNDER SEAL]

## CONFIDENTIAL COVER SHEET–FALSE CLAIMS ACTION

CASE NUMBER:
CGC-07-463330

**INSTRUCTIONS: This civil action is brought under the False Claims Act, Government Code section 12650 et seq. The documents filed in this case are under seal and are confidential pursuant to Government Code section 12652(c).**

**This Confidential Cover Sheet must be affixed to the caption page of the complaint and to any other paper filed in this case until the seal is lifted.**

**You should check with the court to determine whether papers filed in False Claims Act cases must be filed at a particular location.**

Seal to expire on (*date*):
July 10, 2007
**UNLESS:**
(1) Motion to extend time is pending; or
(2) Extended by court order

1. The document to which this cover sheet is affixed is:
   a. [ ] Complaint for damages for violation of the False Claims Act
   b. [✓] *Civil Case Cover Sheet* (form 982.2(b)(1))
   c. [ ] Motion for an extension of time to intervene
   d. [ ] Affidavit or other document in support of the motion for an extension of time
   e. [ ] Order extending time to intervene (*specify date order expires*):
   f. [ ] Other order (*describe*):

   g. [ ] Notice from the Attorney General of additional prosecuting authority that may have access to the file
   h. [ ] Other (*describe*):

2. This *Confidential Cover Sheet* and the attached document must each be separately file-stamped by the clerk of the court.

Date: May 11, 2007



Form Adopted for Mandatory Use
Judicial Council of California
MC-060 [Rev. January 1, 2007]

CONFIDENTIAL COVER SHEET
FALSE CLAIMS ACTION

Gov. Code, § 12652(c);
Cal. Rules of Court, rules 2.570-2.573
www.courtinfo.ca.gov
American LegalNet, Inc.
www.FormsWorkflow.com

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
NANCY HERSH, ESQ.
HERSH & HERSH, A Professional Corp.
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102-6396
TELEPHONE NO.: (415) 441-5544 FAX NO.:
ATTORNEY FOR (Name): Plaintiff

CALIFORNIA STATE BAR NO.: 49091

FOR COURT USE ONLY

ENDORSED
FILED
San Francisco County Superior Court
MAY 11 2007
GORDON PARK-LI, Clerk
BY: PARAM NATT Deputy Clerk

SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO
STREET ADDRESS: 400 McAllister Street
MAILING ADDRESS: San Francisco, CA 94102
CITY AND ZIP CODE:
BRANCH NAME: Unlimited Jurisdiction

CASE NAME: VICENTE v. ELI LILLY AND COMPANY

CASE NUMBER: CGC-07-463338

JUDGE:
DEPT:

**CIVIL CASE COVER SHEET**

[X] Unlimited (Amount demanded exceeds $25,000) [ ] Limited (Amount demanded is $25,000 or less)

**Complex Case Designation**

[ ] Counter [ ] Joinder

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

*Items 1–5 below must be completed (see instructions on page 2).*

1. Check one box below for the case type that best describes this case:

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**Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)**
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**Miscellaneous Civil Petition**
- [ ] Partnership and corporate governance (21)
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   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [ ] Substantial amount of documentary evidence
   d. [ ] Large number of witnesses
   e. [ ] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
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3. Type of remedies sought *(check all that apply)*:
   a. [X] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [ ] punitive
4. Number of causes of action *(specify)*: 4
5. This case [ ] is [X] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: May 11, 2007
RACHEL ABRAMS
(TYPE OR PRINT NAME)

▶ _____
(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

**NOTICE**
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CIVIL CASE COVER SHEET

Cal. Rules of Court, rules 3.220, 3.400–3.403;
Standards of Judicial Administration, § 19
www.courtinfo.ca.gov

4010

CASE NUMBER: CGC-07-453338 (UNDER SEAL) VS. UNDER SEAL

## NOTICE TO PLAINTIFF

A Case Management Conference is set for

DATE: OCT-12-2007

TIME: 9:00AM

PLACE: Department 212
400 McAllister Street
San Francisco, CA 94102-3680

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference.

However, it would facilitate the issuance of a case management order **without an appearance** at the case management conference if the case management statement is filed, served and lodged in Department 212 twenty-five (25) days before the case management

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state.

## ALTERNATIVE DISPUTE RESOLUTION POLICY REQUIREMENTS

**IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE PARTICIPATE IN EITHER MEDIATION, JUDICIAL OR NON-JUDICIAL ARBITRATION, THE EARLY SETTLEMENT PROGRAM OR SOME SUITABLE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A MANDATORY SETTLEMENT CONFERENCE OR TRIAL.** (SEE LOCAL RULE 4)

Plaintiff must serve a copy of the Alternative Dispute Resolution Information Package on each defendant along with the complaint. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the Alternative Dispute Resolution Information Package prior to filing the Case Management Statement.

**[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]**

Superior Court Alternative Dispute Resolution Coordinator
400 McAllister Street, Room 103
San Francisco, CA 94102
(415) 551-3876

See Local Rules 3.6, 6.0 C and 10 D re stipulation to commissioners acting as temporary judges

# SUPERIOR COURT OF CALIFORNIA
# COUNTY OF SAN FRANCISCO

400 McAllister Street, San Francisco, CA 94102-4514

| | |
|---|---|
| Plaintiff<br>v.<br>Defendant | Case No. _____<br>**STIPULATION TO ALTERNATIVE DISPUTE RESOLUTION** |

**The parties hereby stipulate that this action shall be submitted to the following alternative dispute resolution process:**

- ☐ **Private Mediation**
- ☐ **Binding arbitration**
- ☐ **Non-binding judicial arbitration**
- ☐ **BASF Early Settlement Program**
- ☐ **Other ADR process (describe)** _____
- ☐ **Mediation Services of BASF**
- ☐ **Judicial Mediation**
  - **Judge** _____
  - **Judge** _____

**Plaintiff(s) and Defendant(s) further agree as follows:**

_____

_____

_____

| Name of Party Stipulating | Name of Party or Attorney Executing Stipulation | Signature of Party or Attorney |
|---|---|---|
| ☐ Plaintiff ☐ Defendant ☐ Cross-defendant | | Dated: _____ |
| Name of Party Stipulating | Name of Party or Attorney Executing Stipulation | Signature of Party or Attorney |
| ☐ Plaintiff ☐ Defendant ☐ Cross-defendant | | Dated: _____ |
| Name of Party Stipulating | Name of Party or Attorney Executing Stipulation | Signature of Party or Attorney |
| ☐ Plaintiff ☐ Defendant ☐ Cross-defendant | | Dated: _____ |

☐ ***Additional signature(s) attached***

# Superior Court of California
## County of San Francisco

## Judicial Mediation Program

### Introducing a new court alternative dispute resolution program that provides judicial mediation of complex civil cases

The Judicial Mediation program offers mediation of complex civil litigation by a San Francisco Superior Court judge familiar with the area of the law that is the subject of the controversy. Cases that will be considered for participation in the program include, but are not limited to professional malpractice, construction, employment, insurance coverage disputes, mass torts and complex commercial litigation. Judicial mediation offers civil litigants the opportunity to engage in early mediation of a case shortly after filing the complaint in an effort to resolve the matter before substantial funds are expended. This program may also be utilized at anytime throughout the litigation process. The panel of judges currently participating in the program includes:

The Honorable David L. Ballati
The Honorable Anne Bouliane
The Honorable Ellen Chaitin
The Honorable John J. Conway
The Honorable Robert L. Dondero
The Honorable Ernest H. Goldsmith
The Honorable Curtis E. A. Karnow
The Honorable Patrick J. Mahoney
The Honorable Tomar Mason
The Honorable James J. McBride
The Honorable Kevin M. McCarthy
The Honorable John E. Munter
The Honorable Ronald Evans Quidachay
The Honorable A. James Robertson, II
The Honorable Mary E. Wiss

Parties interested in judicial mediation should file the Stipulation to Alternative Dispute Resolution form attached to this packet indicating a joint request for inclusion in the program and deliver a courtesy copy to Dept. 212. A preference for a specific judge may be indicated. The court Alternative Dispute Resolution Coordinator will facilitate assignment of cases that qualify for the program.

Note: Space is limited. Submission of a stipulation to judicial mediation does not guarantee inclusion in the program. You will receive written notification from the court as to the outcome of your application.

Superior Court Alternative Dispute Resolution
400 McAllister Street, Room 103, San Francisco, CA 94102
(415) 551-3876

12/15/06

# Alternative Dispute Resolution (ADR) Information Package

# Alternatives to Trial

# Here are some other ways to resolve a civil dispute.

The plaintiff must serve a copy of the ADR information package on each defendant along with the complaint. (CRC 201.9(c))

Superior Court of California
County of San Francisco

## Introduction

Did you know that most civil lawsuits settle without a trial?

And did you know that there are a number of ways to resolve civil disputes without having to sue somebody?

These alternatives to a lawsuit are known as alternative dispute resolutions (ADR). The most common forms of ADR are mediation, arbitration and case evaluation. There are a number of other kinds of ADR as well.

In ADR, trained, impartial persons decide disputes or help parties decide disputes themselves. These persons are called neutrals. For example, in mediation, the neutral is the mediator. Neutrals normally are chosen by the disputing parties or by the court. Neutrals can help parties resolve disputes without having to go to court.

ADR is not new. ADR is available in many communities through dispute resolution programs and private neutrals.

## Advantages of ADR

ADR can have a number of advantages over a lawsuit.

- *ADR can be speedier.* A dispute often can be resolved in a matter of months, even weeks, through ADR, while a lawsuit can take years.
- *ADR can save money.* Court costs, attorneys fees, and expert fees can be saved.
- *ADR can permit more participation.* The parties may have more chances to tell their side of the story than in court and may have more control over the outcome.
- *ADR can be flexible.* The parties can choose the ADR process that is best for them. For example, in mediation the parties may decide how to resolve their dispute.
- *ADR can be cooperative.* This means that the parties having a dispute may work together with the neutral to resolve the dispute and agree to a remedy that makes sense to them, rather than work against each other.

- *ADR can reduce stress.* There are fewer, if any, court appearances. And because ADR can be speedier, and save money, and because the parties are normally cooperative, ADR is easier on the nerves. The parties don't have a lawsuit hanging over their heads for years.

- *ADR can be more satisfying.* For all the above reasons, many people have reported a high degree of satisfaction with ADR.

Because of these advantages, many parties choose ADR to resolve a dispute, instead of filing a lawsuit. Even when a lawsuit has been filed, the court can refer the dispute to a neutral before the parties' position harden and the lawsuit becomes costly. ADR has been used to resolve disputes even after a trial, when the result is appealed.

## Disadvantages of ADR

ADR may not be suitable for every dispute.

- If ADR is binding, the parties normally give up most court protections, including a decision by a judge or jury under formal rules of evidence and procedure, and review for legal error by an appellate court.

- There generally is less opportunity to find out about the other side's case with ADR than with litigation. ADR may not be effective if it takes place before the parties have sufficient information to resolve the dispute.

- The neutral may charge a fee for his or her services.

- If a dispute is not resolved through ADR, the parties may have to put time and money into both ADR and a lawsuit.

- Lawsuits must be brought within specified periods of time, known as statutes of limitation. Parties must be careful not to let a statute of limitations run out while a dispute is in an ADR process.

# *NATIONAL REGISTERED AGENTS, INC.*

## *SERVICE OF PROCESS SUMMARY TRANSMITTAL FORM*

To: MICHAEL J. HARRINGTON
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER
INDIANAPOLIS, IN 46285-0000

SOP Transmittal # CA51043

(800) 767-1553 - Telephone
(609) 716-0820 - Fax

Defendant: ELI LILLY AND COMPANY
(Entity Served)

Enclosed herewith are legal documents received on behalf of the above captioned entity by National Registered Agents, Inc. or its Affiliate in the State of CALIFORNIA on this 22 day of August , 2007 . The following is a summary of the document(s) received:

1. **Title of Action:** Plaintiff and Defendant Under Seal (See Package)

2. **Document(s) served:**

M. J. HARRINGTON
AUG 24 2007

| | | |
|---|---|---|
| X Summons | __ Subpoena | __ Injunction |
| X Complaint | __ Third Party Complaint | __ Notice of |
| __ Petition | __ Demand for Jury Trial | __ Mechanics Lien |
| __ Garnishment | __ Default Judgement | __ Other: |

3. **Court of Jurisdiction/ Case & Docket Number:** San Francisco County Superior Court, Unlimited Jurisdiction
CGC-07-463330

4. **Amount Claimed, if any:**

5. **Method of Service** (select one):

| | | | |
|---|---|---|---|
| X Personally served by: | X Process Server | __ Deputy Sheriff | __ U. S Marshall |
| __ Delivered Via: | __ Certified Mail (Envelope enclosed) | __ Regular Mail (Envelope enclosed) | __ Facsimile |
| __ Other (Explain): | | | |

6. **Date and Time of Service:** 8/22/2007 4:17:27 PM PST (GMT -8)

7. **Appearance/Answer Date:** 30 Days

8. **Plaintiff's Attorney:** (Name, Address & Telephone Number)
Nancy Hersh
Hersh & Hersh, A Professional Corporation
601 Van Ness Avenue
Suite 2080
San Francisco, CA 94102
(415) 441-5544

9. **Federal Express Airbill #** 790812034891

10. **Call Made to:** Not required

11. **Special Comments:**
Confidential Civil Cover Sheet - False Claims Action

**NATIONAL REGISTERED AGENTS, INC.**

**Copies To:** FAX: 3172766221
MICHAEL J. HARRINGTON
LILLY CORPORATE CENTER
INDIANAPOLIS, IN 46285-0000

Transmitted by: Joan Petty



ORIGINAL

MC-060

ATTORNEY (Name, state bar number, and address):
NANCY HERSH, ESQ., SBN 49091
HERSH & HERSH, A Professional Corporation
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102-6388
TELEPHONE NO.: 415-441-5544 FAX NO. (Optional):
E-MAIL ADDRESS (Optional):
ATTORNEY FOR: ☑ PLAINTIFF ☐ OTHER (specify):

FOR COURT USE ONLY

ENDORSED
FILED
San Francisco County Superior Court
MAY 11 2007
GORDON PARK-LI, Clerk
BY: PARAM NATT
Deputy Clerk

SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO
STREET ADDRESS: 400 McAllister Street
MAILING ADDRESS:
CITY AND ZIP CODE: San Francisco, CA 94102
BRANCH NAME: Unlimited Jurisdiction

PLAINTIFF: [UNDER SEAL]

DEFENDANT: [UNDER SEAL]

CASE NUMBER:
CGC-07-463330

# CONFIDENTIAL COVER SHEET–FALSE CLAIMS ACTION

**INSTRUCTIONS: This civil action is brought under the False Claims Act, Government Code section 12650 et seq. The documents filed in this case are under seal and are confidential pursuant to Government Code section 12652(c).**

**This Confidential Cover Sheet must be affixed to the caption page of the complaint and to any other paper filed in this case until the seal is lifted.**

**You should check with the court to determine whether papers filed in False Claims Act cases must be filed at a particular location.**

Seal to expire on (*date*):
July 10, 2007
**UNLESS:**
(1) Motion to extend time is pending; or
(2) Extended by court order

1. The document to which this cover sheet is affixed is:
   a. ☐ Complaint for damages for violation of the False Claims Act
   b. ☑ *Civil Case Cover Sheet* (form 982.2(b)(1))
   c. ☐ Motion for an extension of time to intervene
   d. ☐ Affidavit or other document in support of the motion for an extension of time
   e. ☐ Order extending time to intervene (*specify date order expires*):
   f. ☐ Other order (*describe*):

   g. ☐ Notice from the Attorney General of additional prosecuting authority that may have access to the file
   h. ☐ Other (*describe*):

2. This *Confidential Cover Sheet* and the attached document must each be separately file-stamped by the clerk of the court.

Date: May 11, 2007



Form Adopted for Mandatory Use
Judicial Council of California
MC-060 [Rev. January 1, 2007]

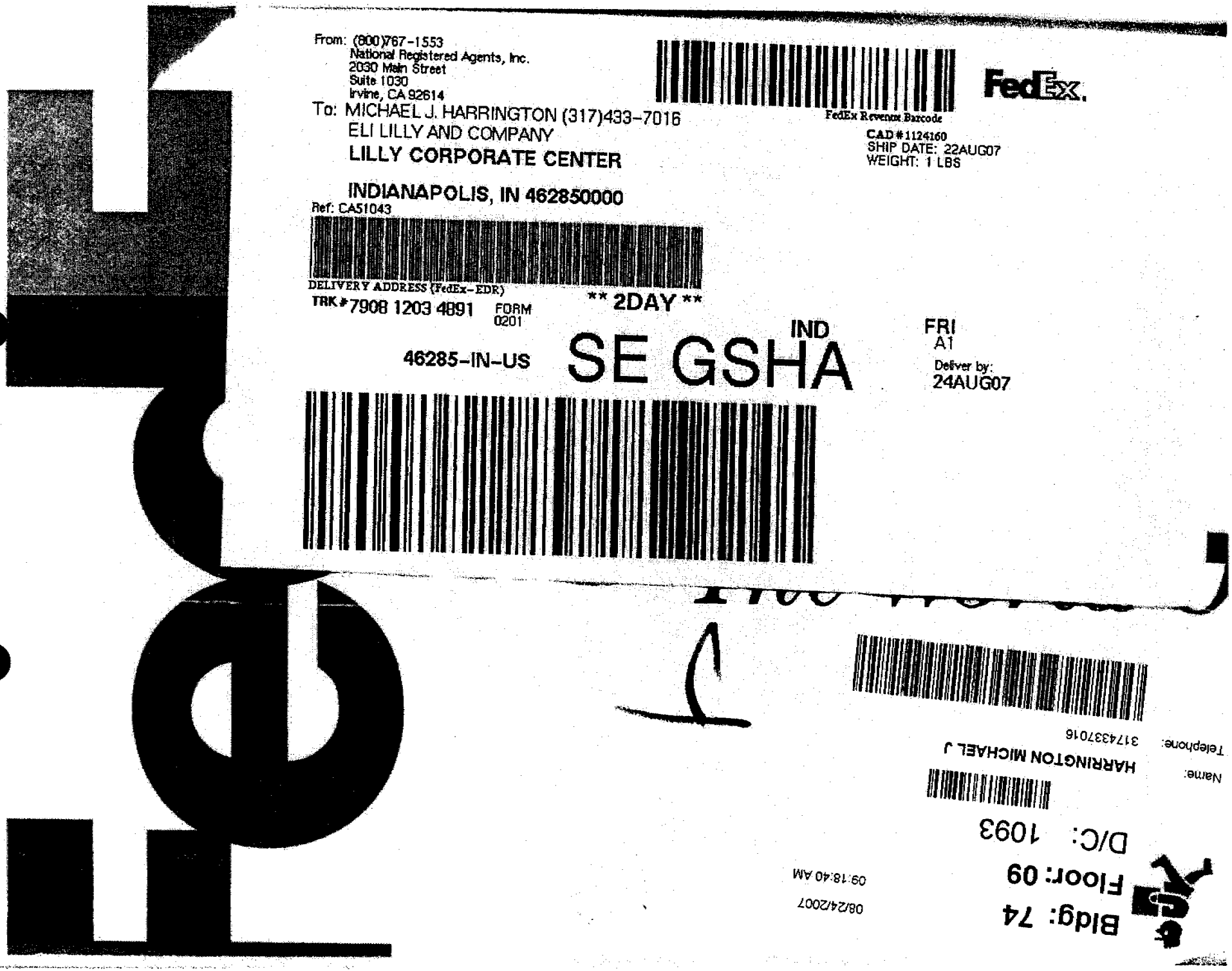
CONFIDENTIAL COVER SHEET
FALSE CLAIMS ACTION

Gov. Code, § 12652(c);
Cal. Rules of Court, rules 2.570-2.573
www.courtinfo.ca.gov
American LegalNet, Inc.
www.FormsWorkflow.com

"UNDE
SEAL

Eli Lilly and Company
c/o National Registered Agents, In.
2030 Main St., Suite 1030
Irvine, CA. 92614

UNDER
AL"



From: (800)767-1553
National Registered Agents, Inc.
2030 Main Street
Suite 1030
Irvine, CA 92614

To: MICHAEL J. HARRINGTON (317)433-7016
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER

INDIANAPOLIS, IN 462850000

Ref: CA51043

DELIVERY ADDRESS (FedEx-EDR)

TRK# 7908 1203 4891 FORM 0201

** 2DAY **

46285-IN-US

IND

SE GSHA

FedEx Revenue Barcode

FedEx.

CAD#1124160
SHIP DATE: 22AUG07
WEIGHT: 1 LBS

FRI
A1

Deliver by:
24AUG07

Name: HARRINGTON MICHAEL J

Telephone: 3174337016

Bldg: 74
Floor: 09
D/C: 1093

08/24/2007 09:18:40 AM

NANCY HERSH, ESQ., State Bar No. 49091
MARK E. BURTON, JR., ESQ., State Bar No. 178400
RACHEL ABRAMS, ESQ., State Bar No. 209316
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue, 2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Attorneys for Plaintiffs



HERSHANDHERSH
A Professional Corporation

**SUPERIOR COURT OF THE STATE OF CALIFORNIA**

**COUNTY OF SAN FRANCISCO**

| | | |
|---|---|---|
| **STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**ELI LILLY AND COMPANY,**<br><br>**Defendant.** | §<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§ | CIVIL ACTION NO.: CGC-07-463338<br><br>**PROOF OF SERVICE** |

HERSHANDHERSH
A Professional Corporation

**PROOF OF SERVICE**

I, Alexandra Guardado, declare:

I am employed in the City and County of San Francisco, California. I am over the age of 18 years and not a party to the within cause; my business address is 601 Van Ness Avenue, Suite 2080, San Francisco, California 94102-6388.

On July 6, 2007, I served the following:

**RELATORS' STATEMENT**

in said action by placing a true copy thereof, enclosed in a sealed envelope, each envelope addressed as follows:

Office of the Attorney General
1300 "I" Street
P.O. Box 944255
Sacramento, CA 94244-2550

X **(BY CERTIFIED U.S. MAIL RETURN RECEIPT REQUESTED)** I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

___ **(BY PERSONAL SERVICE)** I served by hand each such envelope to the addressee above.

___ **(BY OVERNIGHT DELIVERY)** I placed a true and correct copy of the document(s) listed above enclosed in a sealed envelope(s), and causing said envelope to be delivered to an overnight delivery carrier with delivery fees provided for, addressed to the person(s) on whom it is to be served.

___ **(BY FAX)** I transmitted via facsimile the document(s) listed above to the fax number(s) set forth above on this date before 5:00 p.m.

I declare under penalty of perjury that the above is true and correct. Executed on July 6, 2007, at San Francisco, California.

/s/ Alexandra Guardado
Alexandra Guardado

NANCY HERSH, ESQ., State Bar No. 49091
MARK E. BURTON, JR., ESQ., State Bar No. 178400
RACHEL ABRAMS, ESQ., State Bar No. 209316
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue, 2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Attorneys for Plaintiffs



HERSHANDHERSH
A Professional Corporation

**SUPERIOR COURT OF THE STATE OF CALIFORNIA**

**COUNTY OF SAN FRANCISCO**

| | | |
|---|---|---|
| **STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually,** | § | CIVIL ACTION NO.: CGC-07-463338 |
| **Plaintiffs,** | § | **PROOF OF SERVICE** |
| **v.** | § | |
| **ELI LILLY AND COMPANY,** | § | |
| **Defendant.** | § | |

**PROOF OF SERVICE**

I, Alexandra Guardado, declare:

I am employed in the City and County of San Francisco, California. I am over the age of 18 years and not a party to the within cause; my business address is 601 Van Ness Avenue, Suite 2080, San Francisco, California 94102-6388.

On July 6, 2007, I served the following:

**RELATORS' STATEMENT**

in said action by placing a true copy thereof, enclosed in a sealed envelope, each envelope addressed as follows:

Office of the Attorney General
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004

___ **(BY CERTIFIED U.S. MAIL RETURN RECEIPT REQUESTED)** I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

__X__ **(BY PERSONAL SERVICE)** I served by hand each such envelope to the addressee above.

___ **(BY OVERNIGHT DELIVERY)** I placed a true and correct copy of the document(s) listed above enclosed in a sealed envelope(s), and causing said envelope to be delivered to an overnight delivery carrier with delivery fees provided for, addressed to the person(s) on whom it is to be served.

___ **(BY FAX)** I transmitted via facsimile the document(s) listed above to the fax number(s) set forth above on this date before 5:00 p.m.

I declare under penalty of perjury that the above is true and correct. Executed on July 6, 2007, at San Francisco, California.

Alexandra Guardado

NANCY HERSH, ESQ., State Bar No. 49091
MARK E. BURTON, JR., ESQ., State Bar No. 178400
RACHEL ABRAMS, ESQ., State Bar No. 209316
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue, 2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Attorneys for Plaintiffs



HERSHANDHERSH
A Professional Corporation

**SUPERIOR COURT OF THE STATE OF CALIFORNIA**

**COUNTY OF SAN FRANCISCO**

| | | |
|---|---|---|
| **STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**ELI LILLY AND COMPANY,**<br><br>**Defendant.** | §<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§ | CIVIL ACTION NO.: CGC-07-463338<br><br>**PROOF OF SERVICE** |

**PROOF OF SERVICE**

I, PORTLAND GRANT, declare:

I am employed in the City and County of San Francisco, California. I am over the age of 18 years and not a party to the within cause; my business address is 601 Van Ness Avenue, Suite 2080, San Francisco, California 94102-6396.

On May 11, 2007, I served the

COMPLAINT FOR DAMAGES [UNDER SEAL]; CIVIL CASE COVER SHEET; CONFIDENTIAL COVER SHEET-FALSE CLAIMS ACTION; CONFIDENTIAL COVER SHEET-FALSE CLAIMS ACTION

in said action by placing a true copy thereof, enclosed in a sealed envelope, each envelope addressed as follows:

Office of the Attorney General
1300 "I" Street
PO Box 944255
Sacramento, CA 94244-2550

X **(BY CERTIFIED MAIL-RETURN RECEIPT REQUESTED)** I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

__ **(BY PERSONAL SERVICE)** I caused such envelope to be delivered by hand to the offices of each addressee above.

__ **(BY OVERNIGHT DELIVERY)** I placed a true and correct copy of the document(s) listed above enclosed in a sealed envelope(s), and causing said envelope to be delivered to an overnight delivery carrier with delivery fees provided for, addressed to the person(s) on whom it is to be served.

__ **(BY FAX)** I transmitted via facsimile the document(s) listed above to the fax number(s) set forth above on this date before 5:00 p.m.

I declare under penalty of perjury that the above is true and correct. Executed on May 11, 2007, at San Francisco, California.

Portland Grant
PORTLAND GRANT

HERSHANDHERSH
A Professional Corporation

NANCY HERSH, ESQ., State Bar No. 49091
MARK E. BURTON, JR., ESQ., State Bar No. 178400
RACHEL ABRAMS, ESQ., State Bar No. 209316
HERSH & HERSH
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601 Van Ness Avenue, 2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Attorneys for Plaintiffs

FILED
San Francisco County Superior Court
MAY 11 2007
GORDON PARK-LI, Clerk
BY: Param Natt
Deputy Clerk

CASE MANAGEMENT CONFERENCE SET
OCT 12 2007 -9:00 AM
DEPARTMENT 212

IMAGED
AUG 28 2007

HERSHANDHERSH
A Professional Corporation

**SUPERIOR COURT OF THE STATE OF CALIFORNIA**

**COUNTY OF SAN FRANCISCO**

| | | |
|---|---|---|
| **STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**ELI LILLY AND COMPANY,**<br><br>**Defendant.** | § | CIVIL ACTION NUMBER<br><br>CGC-07-463338<br>**COMPLAINT FOR DAMAGES**<br><br>**[UNDER SEAL]** |

Qui tam Plaintiff/Relator Jaydeen Vicente ("Plaintiff-Relator"), on behalf of the State of California and herself individually, for her Complaint against Defendant Eli Lilly and Company ("Lilly" or "Defendant Lilly") alleges based upon personal knowledge and relevant documents, as follows:

## I. NATURE OF ACTION

1. This is an action to recover damages and civil penalties on behalf of the State of California arising from 1) intentionally false and/or fraudulent records caused to be presented and 2) statements and records caused to be made to get false claims paid by Defendant Lilly and/or its agents, employees and co-conspirators to California's Medicaid

Program, commonly known as Medi-Cal, in violation of the California False Claims Act, Cal. Govt. Code §12650 *et seq*.

2. The instant matter arises in principal part from Defendant Lilly's nationwide, coordinated deceptive off-label marketing and promotional practices for its potent atypical antipsychotic Zyprexa. Specifically, Lilly devised, and successfully implemented through its divisions of Zyprexa sales representatives, a marketing campaign calculated to increase physicians' off-label use of Zyprexa within the State of California to treat symptoms, mood disorders and patients within age demographics for which the drug has not received FDA approval, nor which has been supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information.

3. The conduct alleged herein shows a pattern of conduct designed to maximize profits at the California Medicaid Program's expense.

4. Lilly's Zyprexa sales representatives were among primary resources used by Lilly to dramatically increase Zyprexa sales for off-label uses to beneficiaries of California's Medicaid program.

5. Lilly organized its Zyprexa sales force into several divisions. One such division was a ***Long Term Care*** ("LTC") sales force consisting of 160 sales persons in 2000 to whom Lilly paid a generous salary and offered personal incentives such as bonus programs in exchange for the unlawful and deceitful off-label promotion of Zyprexa in the elderly demographic. Lilly's Zyprexa LTC sales representatives' sole objective was to promote the potent and expensive antipsychotic within the LTC market for a litany of unapproved and untested off-label medical uses for the explicit and illicit purpose of increasing market share and revenues derived from this coveted patient population – which the drug was not, and still is not, FDA-approved to treat.

6. Lilly provided extensive training and Zyprexa product support (including advertising materials and exaggerated and misleading pro-Zyprexa studies) to its "specialty" LTC sales force tailored to promoting Zyprexa's safety and efficacy to geriatric

healthcare providers (closed-end pharmacies, geriatric physicians and LTC facilities) through misleading, deceptive and wanton means. In furtherance of its Zyprexa sales scheme, Lilly also paid kickbacks masquerading as speaker fees, honoraria, unrestricted educational grants, entertainment and other in-kind forms. Lilly disbursed its valuable kickbacks with the understanding and specific intent that the geriatric healthcare providers to which they were paid would increase their usage and/or dosage of Zyprexa in elderly LTC facilities. Lilly engaged in this conduct purposefully, with the foreseeable impact of increasing Zyprexa off-label sales revenues derived in principal part from Medicaid programs all across the country, including Medi-Cal.

7. Lilly's illegal and zealous off-label over promotion of Zyprexa was calculated to increase sales of Zyprexa in the elderly population for dementia symptoms, agitation, insomnia and many other generic symptoms with reckless disregard for the safety of the elderly patients prescribed the drug for such untested and unapproved uses which Lilly targeted in its off-label marketing campaign.

8. Plaintiff-Relator has personal knowledge that Lilly engaged in the Zyprexa off-label promotional effort in Long Term Care ("LTC") facilities and in primary care physicians' offices in the State of California as well as nationwide, as she was employed by Lilly as a LTC sales representative in the Northern California region.

9. Lilly's illegal Zyprexa marketing campaign was calculated to, and did, cause billions of dollars of Zyprexa to be prescribed off-label to vulnerable, elderly long term care nursing home residents and adults (who at most were depressed or presented with other mood-related symptoms or illnesses) since Lilly's drug was released on the prescription drug market in 1996. These expensive prescription purchases were funded, in whole or in part, principally by government-funded healthcare programs including Medi-Cal.

10. Lilly's off-label LTC Zyprexa scheme succeeded. Lilly's LTC sales force was the most successful of all Lilly's Zyprexa sales divisions. Specifically, Plaintiff-Relator gained personal knowledge from Lilly corporate employees during Lilly's regional and national sales conferences and from the sales data Lilly made available to her, that the

Zyprexa revenues generated per LTC sales representative far exceeded the Zyprexa revenues generated per sales representative in any of its other Zyprexa sales division.

11. The purchases of the billions of dollars of dangerous, potent off-label Zyprexa prescriptions in California were funded in principle part by and through the, *inter alia*, Medi-Cal program. The State of California would not have funded millions of dollars of Zyprexa purchases since the drug's launch in 1996 but for Lilly's unlawful, intentionally deceitful and aggressive marketing tactics alleged herein.

12. Lilly's conduct endangered the health of Medi-Cal beneficiaries by placing them at great risk of harm of developing serious, irreversible and even life-threatening side effects that were known to Lilly at all times relevant to this Complaint, but which Lilly intentionally concealed to protect its windfall of billions of dollars of annual Zyprexa sales revenues.

13. Hundreds of thousands of Medi-Cal beneficiaries have now and continue to fall victim to serious, irreversible diseases and or potentially life threatening medical conditions including diabetes and hyperglycemia, in addition to the substantially increased risk of death for certain patients, especially elderly patients with dementia, as a direct and proximate cause of Lilly's illegal and capricious Zyprexa marketing tactics.

14. The California False Claims Act (Cal. Gov. Code §§ 12650 et seq.) permits any person discovering a fraud perpetrated against the State of California to bring an action for herself and for the State of California and to share in any recovery. Plaintiff-Relator commences this *qui tam* action individually and on behalf of the State of California to recover treble damages and civil penalties under the California False Claims California False Claims Act, Cal. Gov. Code §§ 12650 et seq.

15. Although unfortunately, California's False Claims Act does not provide for a recovery of the exorbitant medical costs to treat the diseases and afflictions Lilly knew Zyprexa would cause, Plaintiff-Relator, on behalf of the State of California, seeks redress against Lilly under the California False Claims Act for each of the hundreds of thousands false claims for reimbursement for the prescription cost of Zyprexa Lilly intentionally and

willfully caused to be submitted to the Medi-Cal program.

## II. PARTIES

16. Plaintiff-Relator brings this action on behalf the State of California to remedy the millions of dollars its Medicaid program has been fraudulently induced to pay as a result of false Zyprexa reimbursement claims submitted by, and caused to be submitted by, Defendant Lilly. The State of California and Plaintiff-Relator Vicente will be collectively referred to as "Plaintiffs."

17. Plaintiff-Relator Vicente is a citizen of the United States and resident of the State of California. She resides at 7 Castle Hill Court, Vallejo, CA, 94591. Plaintiff-Relator Vicente was employed by Lilly for three years beginning in February 2000 as a Long Term Care Pharmaceutical Representative in the State of California. In this capacity, Lilly trained, paid and directed Plaintiff-Relator to promote Zyprexa off-label to treat elderly LTC skilled nursing facility residents in Northern California. Lilly offered Zyprexa selling incentives to Plaintiff-Relator by structuring a bonus program available to her based upon sales revenues of Zyprexa generated in her territory from LTC sales.

18. Defendant Eli Lilly and Company is an Indiana corporation and has its principle place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. At all times relevant hereto, Lilly was engaged in the business of licensing, manufacturing, distributing, promoting and/or selling, either directly or indirectly, the pharmaceutical prescription drug Zyprexa throughout the State of California and the United States, through its third party agents and/or employees, including its LTC sales force and its primary care physician sales divisions.

## III. FILING UNDER SEAL

19. In accordance with California False Claims Act, Cal. Gov. Code §12652(c)(2) and California Rules of Court, Rule 2.570, this complaint is filed *in camera* and will remain under seal and will not be served on the Defendant Lilly until the Court so orders. A copy of the complaint and written disclosure of substantially all material evidence and information the Plaintiff possesses have been served on the State of California

pursuant to California False Claims Act, Cal. Gov. Code §12652(c)(3).

## IV. ORIGINAL SOURCE

20. Through her employment as Lilly "specialty" LTC sales representative assigned to the Northern California region, Plaintiff-Relator Vicente was trained and employed by Lilly to promote Zyprexa for off-label uses, specifically, for use in the elderly LTC demographic, as is alleged with particularity *infra*, Plaintiff-Relator acquired a wealth of direct, independent and non-public knowledge of Lilly's unlawful acts described in this Complaint.

21. Plaintiff-Relator gained personal knowledge of Lilly's kickback payments to physicians made for the purpose, and with the intent to, induce those physicians (both geriatric physicians and PCPs) to prescribe Zyprexa to his or her Medicaid beneficiary patients.

22. Plaintiff-Relator has personal knowledge of Lilly's corporate endorsement of this unlawful national off-label Zyprexa marketing scheme for the LTC market as well as other markets including primary care and also has personal knowledge of the specific Lilly corporate personnel responsible for implementing Zyprexa's off-label marketing.

23. Accordingly, Plaintiff-Relator is an "original source" of the non-public information alleged in this Complaint within the meaning of California False Claims Act, Cal. Gov. Code §12652(d)(3)(A) and (B), Plaintiff-Relator is concurrently providing to the State Attorney General a disclosure statement summarizing and supported by known material evidence in accordance with the provisions of California False Claims Act, Cal. Gov. Code §12652(c)(3).

## V. JURISDICTION

24. This Court has jurisdiction over the subject matter of this civil action. The State of California is a named plaintiff.

25. This Court has jurisdiction over Defendant Lilly because the drug company can be found in, is authorized to transact business in, and is now transacting business in the State of California.

## VI. THE MEDI-CAL AND MEDICARE PART D PRESCRIPTION DRUG REIMBURSEMENT BENEFIT

### A. The Medi-Cal Program

29. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded by Medicaid up until January 1, 2006 was funding for the prescription drug needs of the Medicaid program beneficiaries.

30. At all times relevant to the Complaint, in most states, Medicaid was an open-ended federal-state matching program. The federal government contributes a fixed percentage of the state's Medicaid costs each year; however, the exact percentage the federal government contributes varies year to year using a formula that takes into account the state's per capita income relative to the national per capita income.

31. The percentage of state contribution the funding of prescription drug purchases, and all other covered Medicaid health benefits, typically amounted to at least 40% at all times relevant to the complaint.

### B. The Medicare Part D Program

32. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States.

33. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

34. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

35. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

36. Pursuant to the Medicare Part D Program, states, including the Plaintiff State of California provide funding for the purchases of beneficiaries of that program's prescription drugs through what is commonly referred to as "claw back" provisions.

**C. Reimbursement Limits on Off-Label Drug Prescriptions**

37. Although Medi-Cal is administered by the State of California, Medi-Cal adheres to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal and state governments will pay for Medicaid programs.

38. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, the eligibility of various drugs for federal financial participation ("FFP"), price controls on prescription drugs and drug manufacturer rebate agreements.

39. According to the Social Security Act, the State of California is entitled to FFP for reimbursement of pharmaceuticals for covered patient drugs. 42 U.S.C.A. §1396r-8. The definition of a "covered outpatient drug" is limited to those drug prescribed to treat medically excepted indications. 42 U.S.C.A. 1396(k)(3). A medically accepted indication is any use approved by the FDA, or supported by one of the three specifically identified compendia. *Id.* (k)(6). The compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the Drugdex

Information System. *Id.* at (g)(1)(b)(i).

40. By way of example, under the Florida Medicaid Program the determination of whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. 1396r-8, Chapter 465 F.S., and the Florida Medicaid Prescribed Drug Services Provider Handbook.

41. In addition to the statutory authority granted by 42 U.S.C. 1396r-8 allowing state Medicaid programs to exclude or otherwise restrict coverage of outpatient prescription drugs, pursuant to the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook to be reimbursed by Medicaid, a drug must be medically necessary and prescribed for medically accepted indications and dosages found in the **(A)** drug labeling ("labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article), the **(B)** American Hospital Formulary Service Drug Information, the **(C)** United States Pharmacopeia-Drug Information or the **(D)** DRUGDEX Information System.

42. Lilly knew or should have known the Medicaid regulations governing prescription drug reimbursement.

42. Whether the use of a drug is medically necessary was material to Medicaid's decision to reimburse for prescription. Consequently, the government would have denied reimbursement for claims made for prescriptions of Zyprexa if it had known the purpose for which the drug had been prescribed was medically unnecessary.

43. Use of Zyprexa, for example, for dementia, or for anxiety or depression in the elderly is not supported by the compendia as medically safe and effective, and therefore should not have been covered by the State of California's Medicaid programs, yet nonetheless, Lilly recklessly has promoted Zyprexa for those and other unauthorized, untested and unproven uses through the methods alleged in this Complaint.

44. Lilly expected and intended its unlawful Zyprexa promotional efforts to cause claims for reimbursement to be submitted to, *inter alia*, Medi-Cal. Lilly designed and implemented its aggressive off-label Zyprexa promotional tactics with the intent to

influence the prescribing choices of long-term care and primary care physicians who treat Medi-Cal beneficiaries. The intended and foreseeable effect Lilly's avaricious scheme was that the Medi-Cal would fund the cost of treatment with Zyprexa through its reimbursement claims system and accordingly, in turn, Lilly would directly and substantially increase its Zyprexa revenue stream at *inter alia* Medicaid expense.

45. Until recently, the State of California was unaware of the unlawful manner in which Lilly promoted Zyprexa off-label within the state and nationally.

46. Under the California False Claims Act, it is unlawful for any "person," as defined by the statute, to submit a false or fraudulent claim to Medicare and Medicaid. The act of submitting a false claim includes by causing another to submit a false claim as well as soliciting, receiving, offering or paying any kickback, bribe or rebate in connection with a Medicaid claim. Cal. Govt. Code §12651.

47. The California False Claims Act provides for penalties of up to $10,000.00 for each violation of the foregoing provisions.

48. Lilly has caused false claims to be submitted to Medicaid for reimbursement through its promotional efforts in violation of the California False Claims Act.

49. In summary, throughout the country and in the State of California, Lilly aggressively and intentionally marketed Zyprexa for non-indicated uses and non-medically necessary uses including for the treatment of general mood and behavior disorders, attention deficit disorder, the attention deficit hyperactivity disorder, depression ***not*** associated with psychosis, sleeplessness, autism, Alzheimer's, dementia and aggression and agitation associated with dementia and Alzheimer's. Further, Lilly has intentionally misrepresented to prescribers who treat Medicaid participants that Zyprexa is safer than less expensive, generic antipsychotics such as Haldol which costs pennies per day rather than the extraordinary expense of Zyprexa.

50. By and through this and other conduct, Lilly caused tens of thousands of prescription reimbursement claims for Zyprexa prescribed for medically unnecessary and non-indicated uses to be submitted to the Medicaid/Medicare programs for reimbursement.

However, the prescription drug reimbursement claims for off-label uses of Zyprexa Lilly caused to be submitted to the Government as a direct result of its unlawfully off-label promotion campaign were not eligible for reimbursement from Medicaid, the VA or CHAMPUS/Tricare (and Medicare Part D, when it came into effect on January 2006) because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute.

51. Lilly engaged in its national Zyprexa promotional blitz with the knowledge that the majority of Zyprexa prescriptions written as a result thereof are reimbursed by government-funded health programs such as Medicaid, as well as with the knowledge that such prescriptions were for non-medically accepted indications and non-medically necessary uses of Zyprexa that fall outside the coverage of Medicaid.

## VII. BACKGROUND

### A. FDA Regulation of Drug Companies and their Marketing Practices

52. As detailed below, Lilly's conduct also materially and wantonly violated the FDA's regulations and federal law governing off-label marketing and truthful labeling and promotion of prescription drugs. Lilly engaged in this profit-driven misconduct for the purpose of deceiving physicians with their false and fraudulent off-label marketing message to cause the submission of false claims for Zyprexa to the State of California.

#### *1) The FDA's Regulation of Promotional Activities of Drug Manufacturers*

53. A prescription drug's product labeling contains the drug's indication. Drug product labeling broadly defined by federal regulation, including 21 C.F.R. § 202.1(k)(2), which provides that drug manufacturers' marketing and promotional materials for their drugs aimed at physicians, *i.e.*, all brochures, handouts, detail aids, slide shows or other such promotional materials, are also defined as "product labeling" and are stringently regulated as such. By law, representations made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any failure to

fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

54. Pharmaceutical promotional materials and presentations lacking in fair balance or that are otherwise false or misleading, violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drugs reference "off-label" uses or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated or are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

55. "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (*e.g.* treating a child with the drug when the drug is approved to treat adults).

56. Lilly materially violated these clear-cut labeling and misbranding regulations to illegally increase sales of its blockbuster drug in the off-label elderly market by and through its marketing and promotional efforts of its LTC sales force in direct-to-physician marketing.

57. Lilly, unable to control and bolster Zyprexa revenues by directly submitting prescription drug reimbursement claims to Medicaid and Medicare, instead launched a campaign intended to increase Government-funded off-label purchases of Zyprexa by defrauding LTC physicians, pediatric physicians and primary care physicians ("PCPs") to prescribe Zyprexa. The natural, intended and foreseeable consequence of such unlawful, premeditated conduct caused physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

58. Each such claim Lilly knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to get claims for Zyprexa paid, constitutes a false claim for which Lilly is accountable under the California False Claims Act.

*2) Federal Law Prohibits Off-Label Marketing To Protect the Health and Safety of Patients*

59. Off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law because of its inherent dangers. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

60. Under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose (notably, however, Lilly's creation of a LTC sales division directly evidences Lilly introduced Zyprexa into interstate commerce with the specific intent that it be used for off-label purposes, *i.e.*, to treat vague cross-over symptoms in the elderly, as pleaded with specificity herein), and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

61. Physicians are not prohibited from prescribing an FDA-approved drug "off-label"; however, pharmaceutical promotional activities and marketing materials and presentations are false or misleading in violation the Food Drug and Cosmetics Act and regulations promulgated hereunder if they advertise "off-label" uses of a drug, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated.

62. When pharmaceutical companies illegally encourage off-label uses for their drugs, the number of prescriptions rises, thereby causing Medicaid and other programs to pay out more for prescriptions that are not eligible for payment. Lilly intended for its "off-label" promotional campaign to improperly increase the submissions of off-label Zyprexa

prescriptions, including such prescriptions reimbursed by the Medicare and Medicaid programs.

63. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

64. Any claim submitted for a drug when the drug was prescribed for an off-label use not only violates Medicare payment rules but also files a fraudulent claim under the False Claims Act. 31 U.S.C. §3802. Claims for Zyprexa prescriptions induced to be written and submitted by Medicaid/Medicare participating pharmacy benefits providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign has caused the State of California to suffer substantial economic harm.

**B. Zyprexa's Limited Indicated Uses**

65. In September of 1996, the FDA approved Zyprexa tablets for use in the treatment of adults of schizophrenia at target doses of 10 mg. per day. In 2001, the Zyprexa tablets were approved for treatment of adults suffering from acute manic episodes associated with bipolar I disorder at dosages of up to 20 mg. per day. In July of 2003, Zyprexa tablets were approved for the short-term treatment of adults suffering from acute manic episodes associated with bipolar I disorder, in combination with lithium or **Depakote (valproic acid)**, with a recommended doses of 10 to 20 mg. per day. In January of 2004, Zyprexa tablets were approved for long-term treatment of adults diagnosed with bipolar disorder in doses of up to 20 mg. per day.

66. In 2001, Lilly launched ZYPREXA Zydis, an orally disintegrating tablet form of Zyprexa. ZYPREXA Zydis was specifically identified as an "opportunity" in Lilly's 2001 LTC Business Plan.

67. ZYPREXA Zydis tablets were made available in 4 strengths: 5 mg, 10 mg, 15 mg, and 20 mg. ZYPREXA Zydis has essentially the same efficacy and safety profile as

regular ZYPREXA tablets, and is indicated by the FDA for the same conditions: schizophrenia, maintenance of treatment response in schizophrenia and acute mania associated with bipolar I disorder in patients experiencing a manic or mixed episode.

68. The purpose of the introduction of the new disintegrating tablet form of Zyprexa was for "Convenient Administration." Because this Zyprexa tablet is formulated to easily dissolve within seconds of being placed in the patient's mouth, the drug was touted by Lilly as an important additional option for treating elderly patients, who may have difficulty swallowing a regular tablet form. In addition, Lilly promoted Zydis as providing a convenient alternative to liquid formulations of other drugs, and because absorption is not affected by food, it can be taken without regard to meals or drinking liquids, although, if patients wanted to drink something along with the medication, they may, but it is not necessary.

69. Lilly provided Plaintiff-Relator with training materials to assist in the promotion of ZYPREXA Zydis in the LTC demographic.

*1) Medical Compendia Limited Supported Uses of Zyprexa*

70. The HFS, the United States Pharmacopeia–Drug Information and the DRUGDEX information system support the use of Zyprexa in adult (not geriatric) schizophrenic or bipolar patients **only**. The uses supported by the three compendia and the FDA approved labeling are collectively defined as Zyprexa's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. § 1396r-8. Neither the compendia cited above nor the FDA-approved labeling supports any use of Zyprexa by the elderly, by children or for treatment of adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

## VIII. PLAINTIFF-RELATOR'S PERSONAL KNOWLEDGE OF LILLY'S SUCCESSFUL, NATIONAL OFF-LABEL ZYPREXA MARKETING AND PROMOTIONAL PRACTICES

71. In or about February 2001, Lilly hired Plaintiff-Relator as a Long Term Care ("LTC"), Specialty, Pharmaceutical Representative.

72. Plaintiff-Relator's hiring came on the heels of one of Lilly's expansions of its LTC sales division. Since Lilly established the LTC sales division, which upon information and belief occurred simultaneously with the drug's launch in 1996, Lilly periodically expanded the LTC sales division.

73. At the time Lilly hired Plaintiff-Relator, there were 160 LTC Zyprexa sales representatives whose territories spanned the United States. See Exhibit "A." Initially, there were only 15 LTC sales representatives. In August 1999 that number was expanded to 59. In March 2000, concomitant with Zyprexa gaining sales momentum in the LTC market, Lilly nearly tripled its LTC sales force to 160. *Id.* Lilly continued to increase the size of its LTC sales force thereafter.

74. Lilly's stated purpose for expanding the LTC division was to, *inter alia*, maximize Zyprexa sales to patients who receive their medications *via* a LTC pharmacy. Indeed, Lilly even disseminated materials to LTC sales representatives overtly referring to the "Golden Opportunity in LTC Care" and the data that supported the vast potential for Zyprexa sales in this off-label market.

75. Lilly maintained a Zyprexa LTC sales division to fulfill one purpose - to aggressively promote Zyprexa on behalf of Lilly to LTC facilities that care exclusively for the elderly, despite the lack of any clinical trials or FDA approval for the use of Zyprexa in the elderly. Plaintiff-Relator gained personal knowledge of these facts during Lilly employment and has evidence substantiating these facts in the Lilly documents she retained from her Lilly employment, some of which are attached hereto as Exhibits. As alleged herein and in the expanded discussion of Lilly and its off-label promotion of Zyprexa in section IX, Lilly trained its LTC sales force to maximize Zyprexa's LTC care revenues.

76. For the duration of her employment with Lilly, Plaintiff-Relator's territory encompassed the LTC market for parts of Northern California, which she covered alone, and the scope of her employment was to promote, market and generate increased revenues from sales of Zyprexa prescriptions written to elderly LTC nursing home residents. Plaintiff-Relator detailed the Stockton Territory within the Sacramento District which

encompassed Modesto, Stockton, Lodi, Mantica, Oakdale, Ripon and the surrounding regions.

77. Plaintiff-Relator was required by Lilly to participate in and to graduate from a rigorous 4 week training course at Lilly's corporate headquarters in Indianapolis, Indiana.

78. There were 17 "new hire" LTC sales representative trainees from all over the United States in Plaintiff-Relator's training class. The LTC sales division was uniform throughout the country. All LTC sales representatives received uniform training, they all received the same Zyprexa marketing materials (of course all geared to selling Zyprexa to elderly patients) and all LTC sales representatives market Zyprexa in the LTC demographic in essentially the same manner, no matter which state and which territory.

79. The first two weeks of training focused on Zyprexa. The training topics included an "introduction" to the drug and what it does, the fundamentals about Zyprexa's competitor drugs and training about why Zyprexa is comparatively superior. LTC trainees were also given studies about Zyprexa, Zyprexa's competitors, Zyprexa's effectiveness compared to placebo and/or other atypicals and other similar studies that trainees were required to memorize. The purpose of memorizing these studies was for the Lilly LTC trainees to cite to and explain in detail these Zyprexa-supporting studies during sales calls on LTC physicians. Plaintiff-Relator was given Lilly training materials in connection with her training and was continuously tested throughout her training to monitor her progress.

80. The second two weeks of the training period focused entirely on how to sell Zyprexa to elderly patients in LTC skilled nursing facilities. In reality, this aspect of Lilly's training was a study in how to successfully market Zyprexa and induce physicians to prescribe Zyprexa to elderly patients to treat symptoms such as agitation, irritability, dementia and the like, all of which constitutes illegal off-label marketing.

81. Among other things, Plaintiff-Relator received extensive training from Lilly corporate training officials on subjects such as how to talk about the drug's efficacy in the treatment of Alzheimer's patients, how to induce physicians to ask "unsolicited" questions about Zyprexa off-label uses and to focus the marketing message on symptoms and

behaviors and Zyprexa's superior efficacy in "Restoring Calm," and that "nothing calms like Zyprexa." The sales materials discussed below carry forward this "Calming" selling message.

82. Lilly reinforced this training by providing mandatory role playing sessions designed to replicate what the LTC sales person would experience in the field when calling on LTC physicians.

83. Among other things, Lilly LTC salespersons including Plaintiff-Relator, engaged in role playing exercises that emulated physician sales calls. Lilly made it a prerequisite to "graduation" from Lilly's initial rigorous 4 month training for each LTC sales representative to receive a passing grade on a *videotaped* role-playing session designed to simulate "real life" marketing calls with LTC physicians.

84. Since Zyprexa has not been approved by the FDA to treat the elderly, Lilly trained its LTC sales persons (through such exercises as role playing) to discuss Zyprexa's efficacy and safety in treating generic symptoms known by Lilly to be commonplace in elderly LTC patients. The primary symptoms LTC sales representatives were trained to focus on were hostility and aggression, and to highlight Zyprexa as the drug of choice to "restore calm" in such agitated patients.

85. Notably, Plaintiff-Relator received scant training on schizophrenia and bi-polar disorders during the four weeks if her comprehensive LTC sales training. Instead, the majority of the training involved geriatric data and information. Lilly's focus on geriatrics over Zyprexa's indicated uses evidences Lilly's illegitimate purpose in maintaining a LTC sales division and reveals its focus and intent to achieve blockbuster off-label sales of Zyprexa. The calculated sales and marketing tactics demonstrate Lilly's conscious aforethought to off-label marketing.

86. Plaintiff-Relator, having worked in the pharmaceutical sales prior to Lilly, vocally questioned her Lilly trainers about the legality of the marketing practices being taught, specifically, she questioned the off-label nature of the Zyprexa marketing campaign promoting Zyprexa's safety and superior efficacy for geriatrics to LTC physicians, nursing

home employees and LTC pharmacies. Plaintiff-Relator was assured that by following Lilly's training on how to deliver the LTC Zyprexa message, off-label regulations would not be violated.

87. The role-playing seminars were not limited to LTC training. Rather, mandatory role-playing occurred at every Lilly sales meeting so sales representatives could "brush up" and hone their skills in delivering the misleading, deceptive and illegal Zyprexa off-label marketing tactics.

88. In addition to communicating such practices during frequent regional and district sales conferences, Lilly engrained its off-label marketing message during once or twice annual national sales meetings. During national sales meetings, specific gatherings, seminars, and training sessions were held solely for the Lilly LTC sales representatives.

89. As is detailed below, once Plaintiff-Relator graduated from training, she was continuously given Zyprexa marketing materials, such as studies, LTC implementation guides and "detail aids" tailored to selling Zyprexa in the geriatric market. Lilly's Zyprexa sales materials were the creation of the Zyprexa Brand Team, the division within Lilly responsible for developing the marketing and promotional selling message for Zyprexa in the United States.

90. Plaintiff-Relator also occasionally received promotional materials distributed by her Lilly manager, Dan Tubridy ("Tubridy"). One egregious example of such materials was a one-page sheet containing 2 form letters (one for Zyprexa and one for Zyprexa Zydis) with "fill in the blanks" to personalize the message to client-target physician and his or her geriatric patients Zyprexa doses and times of administration. See Exhibit "B." The letter's purpose was to suggest to the physician that his or her patients' Zyprexa dosage should be increased to reduce "nursing time and effort." Tubridy instructed Plaintiff-Relator to pass out this form letter to her target-physicians to induce an increase in Zyprexa dosage, which translated directly to increased Zyprexa sales revenues, by promoting Zyprexa's known side effect of somnolence. Promotion of Zyprexa as a chemical restraint for difficult, agitated elderly patients was not only illegal unsolicited off-label marketing, but also a wanton

derogation of patients' fundamental human rights.

91. Lilly's myopic focus and goal of driving Zyprexa off-label sales is evidenced by the convoluted manner in which LTC sales representatives' performance was evaluated. Job performance hinged entirely upon each LTC representatives *total sales revenues* generated by LTC Zyprexa purchases in her Northern California territory. Lilly's tunnel vision focus on salespersons profits, rather than number of prescriptions written evidences the avaricious nature of Lilly's illegal marketing pursuit, as it shows salespersons were expected not only to increase market share, but to increase dosages and/or frequency to rive up profits.

92. Plaintiff-Relator was continuously employed as a Lilly LTC sales representative for three years until on or about June 2003. At that time, she voluntarily resigned from her employment to accept a higher-paying pharmaceutical sales representative position with another pharmaceutical company. Plaintiff-Relator began pursing a career change while still a Lilly employee after Lilly executives rebuffed her attempts to rectify the unethical and illegal Zyprexa sales practices implemented and mandated by her Lilly Supervisor, Dan Tubridy.

93. Indeed, prior to leaving Lilly's employ, Plaintiff-Relator submitted to Lilly corporate a 3 page summary documenting all of Tubridy's illegal and unethical conduct. Exhibit "C." Lilly's rebuffed Plaintiff-Relator's attempt to right the wrongs of her manager, simply giving Tubridy a meaningless "warning," which was tantamount to a corporate endorsement of Tubridy's illegal, but successful Zyprexa sales methods. Soon thereafter, Plaintiff-Relator began seeking employment with another pharmaceutical company.

## IX. ADDITIONAL FACTUAL BASIS OF LILLY'S ILLEGAL OFF-LABEL MARKETING OF ZYPREXA FOR ELDERLY OFF-LABEL USES AND TO PRIMARY CARE PHYSICIANS FOR OFF-LABEL USE TO TREAT NON-SCHIZOPHRENIC OR BIPOLAR ADULTS

94. As alleged supra in § VII B, Zyprexa is indicated to treat an exceptionally small subset of the United States population. Indeed, less than 7% of the United States'

adult population has been diagnosed with one of the rare mental illness for which Zyprexa is indicated for the treatment of symptoms relating thereto – schizophrenia and bipolar disorder.

95. It is not by stroke of luck that Zyprexa has been Lilly's largest selling drug for a number of years and has generated astounding blockbuster revenues for the drug company. For years, Zyprexa generated several billions of dollars of revenue for the company and was among the top ten best selling drugs in the world. In 2003, Zyprexa sales rose to $4.4 billion and assumed the rank of world's fifth best selling drug.

96. Rather, from the outset, Lilly recognized the promotion of Zyprexa's not medically accepted indications and not medically necessary uses as the key to Zyprexa's blockbuster success, i.e., promoting the use of Zyprexa to treat off-label demographics who present with symptoms akin to those exhibited by patients diagnosed with those exceedingly rare mental illnesses – depression, sleeplessness, agitation: 1) elderly LTC residents, 2) depressed and distracted adults who are not diagnosed with schizophrenia or bipolar disorder and 3) children with conditions such as ADHD, autism, mood disorders and disruptive children. Lilly devised this game plan despite its awareness of numerous serious treatment emergent side effects caused by Zyprexa including diabetes, hyperglycemia, extraordinary weight gain and metabolic syndrome, to name a few.

97. Indeed, Lilly funded calculated studies with methodologies intended to contrive positive clinical data about Zyprexa to ensure Zyprexa's numerous, dangerous and even deadly side effects were kept from public purview.

98. Lilly succeeded. Zyprexa's incredible revenues and sales ranking directly stems from the drug's dangerous overuse off-label that have not been found by the FDA or medical compendia to be safe or effective. This dangerous overuse is directly attributable to Lilly's illegal off-label promotional tactics.

99. Upon information and belief, based upon the foregoing, Lilly began planning its national, aggressive off-label marketing campaign for Zyprexa even before Zyprexa had received FDA approval. In this regard, Lilly's devised a strategy prior to Zyprexa's launch

to market the drug not only for use with elderly and children, but also for a constellation of broad symptoms in the broad realm of mood and thought disorders, a strategy that gave rise to an ongoing pattern of false and misleading conduct.

100. This conduct directly and proximately resulted in both the submissions of claims for not medically accepted indications and not medically necessary uses of Zyprexa to Medicaid, Medicare, VA and CHAMPUS/Tricare programs in California and throughout the country as well as adverse health effects among participants of those programs.

101. Through this planning Lilly funded clinical studies for Zyprexa, for on and off-label uses, which ultimately Lilly planned to be used by its sales representatives to promote Zyprexa. Indeed, Plaintiff-Relator was given such studies by Lilly with the expectation that she learn the details of the studies backwards and forwards and use the contrived results of the studies in promoting Zyprexa off-label.

102. Lilly furthered its illegal avaricious Zyprexa business plan by creating a deceptive and misleading marketing campaign to create a LTC market for Zyprexa, among other off-label markets. Lilly falsely touted Zyprexa's superior efficacy in treating the generic mood and behavioral symptoms of schizophrenia and bipolar disorder; symptoms that Lilly knew were also prolific in the elderly population.

103. The purpose of the deceptive scheme was to create the misimpression that geriatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category were Zyprexa candidates, thereby creating a broad, ill-defined market for Zyprexa in the elderly demographic.

104. Lilly tweaked the message slightly for its other sales divisions, such as its primary care physician sales force, to achieve the same impact - to create the misimpression that adult and pediatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category would benefit from being prescribed Zyprexa in increasing doses, thereby creating an across the board off-label for Zyprexa among patients who relied upon Medicaid, Medicare, the VA and/or CHAMPUS/Tricare to fund their necessary prescription drug needs.

**A. Lilly's Calculated Training Of Zyprexa Sales Representatives to Successfully Market Zyprexa Off-Label to, *inter alia*, Medicaid/Medicare Beneficiaries**

105. Lilly's scheme was highly successful. Data shows that well over half of all dollars spent on Zyprexa is spent on non-medically accepted or not medically necessary uses. Moreover, Zyprexa has been prescribed to more than 12 million people worldwide since the atypical antipsychotic's launch in 1996. Crucial to this Blockbuster success was Lilly's aggressive marketing of Zyprexa for elderly use through its LTC sales division, which consisted chiefly of exaggerating the drug's uses, while concealing its life-threatening side effects.

106. Lilly created complicated marketing structures that appeared independent from their proprietary of promotion forces.

107. Lilly sales representatives were expected in the course and scope of their employment to identify specific doctors (*i.e.* physicians who were already prescribing large volumes of Zyprexa or physicians whose antipsychotic "business" Lilly wanted to obtain) to recruit and communicate Lilly's interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Zyprexa often were given substantial funds by Lilly in the form of research grants, many unrestricted. These funds were in reality kickback paid to induce the physicians' use of Zyprexa.

108. Lilly engaged in this duplicitous conduct to create the false perception that respected physicians were using and investigating Zyprexa's efficacy in non-medically accepted and not medically necessary uses on their own initiative, and not as a result of Lilly's marketing activities. And in addition to providing free travel to resorts, free lodging and free meals, Lilly also paid these physicians to give talk segment medical education seminars, advisory boards, consultants meetings, speakers bureaus and similar events that favorably discussed not medically accepted and not medically necessary uses of Zyprexa.

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*1) **Promotion to the Elderly***

109. The generic symptoms Lilly unlawfully promoted Zyprexa to treat mimicked those of dementia and/or Alzheimer's, including agitation, anxiety, and insomnia. By marketing the drug for the treatment of ***symptoms*** for which Zyprexa was not approved, Lilly violated strict FDA labeling regulations detailed *infra*.

110. Lilly encouraged use of Zyprexa in the elderly demographic to treat multiple symptoms that might be categorized as relating to dementia and/or Alzheimer's. To assist in these efforts, Lilly created patient profile detail aids whose focus was on "behavior treatment" such as agitation, suspiciousness, depressive mood, anxiety, and lack of concentration. By focusing on symptoms rather than the diagnoses of schizophrenia or bi-polar disorder, Lilly intended to overcome Zyprexa's lack of any FDA approved market for Zyprexa in the LTC demographic.

111. Lilly propagated the intentionally misleading message that Zyprexa was indicated for the treatment of dementia by directing its sales force to focus on behavioral and cognitive symptoms such as anxiety, depression, agitation during physician sales calls.

112. Among the most common, treatment-emergent adverse ***side effects*** of Zyprexa and the other atypical antipsychotics is ***somnolence***. Somnolence is defined as sleepiness, the state of feeling drowsy, ready to fall asleep. Within its drug class, Zyprexa is the most heavily sedating.

113. One approach Lilly devised for its LTC sales representatives was to market Zyprexa's somnolence side effects as method to reduce patient care hours by essentially chemically restraining demanding elderly patients.

114. Indeed, Lilly preyed upon the fact that providing care to elderly LTC residents who typically exhibit combative behavior and aggression is considerably stressful, frustrating and time consuming.

115. By way of example, Plaintiff-Relator and other Lilly LTC sales representatives were given studies by Lilly to distribute to LTC staff espousing ostensibly clinical evidence that elderly patients prescribed Zyprexa required fewer skilled nursing

staff hours than patients prescribed other competing medications. One such study was Olanzapine Treatment of Psychotic and Behavioral Symptoms in Patients With Alzheimer Disease in Nursing Care Facilities, *Archives of General Psychiatry*, Vol. 57, pg. 968 (Oct. 2000) See Exhibit "N." Plaintiff-Relator and other Lilly LTC sales representatives were told to point directly to pg. 971 of this study and read:

> "A statistically significant reduction in caregiver distress, measured by the sum of the Occupational Disruptiveness scores for Agitation/Aggression, Hallucinations, and Delusions (Core Disruptiveness) was seen for patients treated with 5 mg/d of olanzapine... Caregivers of patients treated with 5 mg/d of olanzapine also had similar reductions in Occupational Disruptiveness associated with Anxiety, Appetite and Eating Disorders, Delusions, Depression/Dysphoria, and Hallucinations items."

116. Lilly LTC sales representatives were taught to create "action" in nursing homes by marketing Zyprexa's "calming" effect. In truth, this was Lilly's thinly-veiled marketing of Zyprexa as an effective **chemical restraint** for demanding, vulnerable, and needy patients.

117. In addition, Plaintiff-Relator's manager disseminated a form letter to the representatives under his supervision and control that touted Zyprexa as providing superior efficacy and safety when compared to placebo and significantly reduced caregiver burden at a dose of 5 mgs daily. See Exhibit "B." This statement was "supported" by a footnote citing a study that ostensibly supported this mendacious marketing of Zyprexa as a chemical restraint. *Id.*

118. The form letter also expressed the medical opinion that the 5 mg. dose of Zyprexa should be administered at 5 pm. *Id.* This was a Lilly-trained "5 at 5" slogan which translated essentially referred to give your patients 5 mg. of Zyprexa at 5 pm and they will sleep through the night eliminating the disruptive late night conduct demanding of caregiver time.

119. Atypical antipsychotics are powerful medications, laden with serious treatment-emergent side effects. Zyprexa is a dangerous drug even when prescribed for on-label use. It is even more dangerous for the elderly. Zyprexa and the other atypical

antipsychotics have not received FDA-approval to treat the elderly because of atypicals' serious risk of harm and the lack of scientific evidence of its safety and efficacy in this population.

120. On April 11, 2005, the FDA issued a public health advisory to alert health care providers, patients, and patient caregivers of its determination based upon clinical studies that using Zyprexa or the other atypicals to treat behavioral disorders in elderly patients with dementia is associated with increased mortality. The FDA's examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).

121. Accordingly, the FDA required Lilly to amend Zyprexa's label to include a "black box warning" of this deadly side effect. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

122. Because of Lilly's promotion of Zyprexa's somnolence side effect as an attribute of the drug, patients were intentionally medicated with incapacitating antipsychotic agents such as Zyprexa to control patient behavior, "restore calm" and reduce the time needed to be spent to treat patients, especially the those patients who required burdensome, time intensive care, as well as those patients who demonstrated "oppositional" and "defiant" behavior.

123. The use of atypical and typical antipsychotic drugs to control the behavior of elderly nursing home residents who are not psychotic constitutes an **unlawful chemical restraint**. Lilly's unlawful and unethical promotion of the use Zyprexa, off-label, as a **chemical restraint** resulted in patients being restrained in a zombie-like state, unable to complain or object. Prescriptions were medically unnecessary

124. The State of California's healthcare programs would not have paid prescription drug reimbursement claims caused to be submitted by Lilly's mendacious and

unlawful marketing of Zyprexa's somnolence side effect had it known the truth.

125. As part of the Zyprexa sales campaign, Lilly disseminated Zyprexa LTC Implementation Guides to its LTC sales representatives. Lilly created a LTC Implementation guide specifically to roll out each new year's version of Lilly's LTC patient profile. See eg Exhibit "E."

126. Lilly's LTC detail aid was a LTC stereotypical patient - an elderly patient representing the agitated, hostile geriatric patients LTC physicians treat everyday. "Rose" was the detail piece used by LTC sales representatives to represent the angry and hostile elderly patient complaining of symptoms such as anxiousness, irritability, mood swings, and disturbed sleep. See e.g. Exhibit "D."

127. The "Rose Jackson" ("Rose") detail aid contained only conspicuously printed wording like "Agitation," "Depressive Symptoms," "Aggression," Irritability," and "Sleeplessness" calculated to imply that Zyprexa was indicated for the treatment of such **symptoms**. *Id*. The top of the front page conveyed the message "Helping you bring dignity to patients' lives." *Id*. Nowhere on this Rose detail aid did Lilly explicitly disclose that Zyprexa's FDA-approval was limited to the treatment symptoms of schizophrenia and bipolar mania and not the other generic symptoms highlighted in print on the detail aid (i.e. sleeplessness, irritability, depressive symptoms). *Id*.

128. The detail piece featured a large color picture of "Rose," an elderly woman composed to appear agitated and combative. *Id*. Lilly's strategy goal for the Rose detail piece was to "encourage doctors to try Zyprexa in patients similar to the one we profile, Rose Jackson. In this way, doctors can see for themselves that Zyprexa **stabilizes symptoms and behaviors safely**."

129. "Rose" was designed to personalize the sales representative's promotion of Zyprexa as the wonder drug to "calm" difficult patients and to reduce patient treatment time. Plaintiff-Relator was instructed to show this image to clients to reinforce the marketing message that Zyprexa can treat his or her angry, agitated and difficult patients.

130. Lilly even disseminated along with the Rose detail aid the marketing

message the sales representative was expected to learn verbatim and then deliver during LTC physician sales calls, which Plaintiff-Relator still recalls to this day. Lilly trained its sales representatives to show the Rose detail aid to physicians and deliver a verbatim sales pitch probe recommending that the physician's patients like Rose are indicated for treatment with Zyprexa and would benefit from commencing a Zyprexa regimen. By way of example, Plaintiff-Relator and other sales representatives would ask leading questions to physicians relayed in the LTC Implementation Guide, such as, "Doctor, does it make sense to use Zyprexa as a first choice for a patient like Rose, since Zyprexa helps to safely stabilize symptoms and behaviors such as agitation, anxiety, hostility, delusions, and resistance to care?" See Exhibit "E."

131. Future iterations of the Zyprexa LTC Implementation Guides similarly helped deliver the message that Zyprexa should be prescribed to treat moods, behaviors and symptoms. By way of example, in the January 2003 "Rose" Detail Aid, Lilly describes to sales representatives, including Plaintiff-Relator, that on the detail aid's cover, "there is also the addition of a couple more mood symptoms, which is to emphasize our unique ability in treating mood." See Exhibit "F."

132. When detailing the Zyprexa 2003 LTC Rose detail piece, sales representatives, including Plaintiff-Relator, were instructed to deliver the message that, "Because Zyprexa treats both symptoms of elevated mood and psychosis, it helps you restore calm to the resident, the staff and even the other residents- the environment will be less disruptive since the resident will be calm instead of yelling, 'Help me-help me.'"

133. Further, on the cover of later versions of the Zyprexa LTC Rose detail piece, along with the symptoms and behaviors, Lilly finally incorporated the language, "ZYPREXA is indicated for the treatment of" and then lists the two approved indications for use for Zyprexa, schizophrenia and acute bipolar mania. Exhibit "G."

134. Among the other duplicitous sales tactics implemented by Lilly at the corporate level involved serious violations of the confidentiality of protected health information safeguarded by the HIPAA regulations as well as breaches of the doctor-patient

privilege.

135. Although Lilly LTC salespersons were evaluated on total Zyprexa sales revenues rendering prescribing physicians, the LTC pharmacies, Lilly LTC sales representatives' relationships with LTC pharmacies were nonetheless pivotal in successfully promoting Zyprexa within the LTC context.

136. Indeed, LTC pharmacies arrange for and bill the State of California' for the drugs prescribed by physicians to LTC facility residents. LTC pharmacies are known as 'closed-door' pharmacies. Closed-door pharmacies are full-service pharmacies, but which exclusively provide prescription drug delivery services to residents of LTC facilities.

137. LTC pharmacies regularly bill Government-funded healthcare plans such as Medicaid for medications prescribed by medical professionals working onsite at the nursing homes.

138. When a patient in a nursing home requires a prescription medication, physicians give written or verbal prescription orders for their patients to nurses. The nurses transmit the prescription orders verbally or by facsimile to the responsible LTC pharmacy clerical data entry personnel to be entered into the LTC pharmacy's computerized order entry system.

139. Once a physician's prescription order is processed in the LTC pharmacy's order entry system, a pharmacist fills the prescription based on the physician's request and the medication is then shipped to LTC skilled nursing home facility where the patient resides.

140. Once the LTC has filled and shipped a prescription, the LTC pharmacy prepares a claim for submission to the Government, including the State of California, seeking reimbursement for the cost of the prescription drug.

141. Lilly knew that the vast majority of elderly LTC residents rely upon, *inter alia*, Medicare and Medicaid to fund in whole or in part their prescription drug costs.

142. Since LTC pharmacies play an integral role in the delivery of prescription drugs to LTC residents, LTC pharmacies were also "clients" of LTC sales representatives